

## REMARKS

Claims 1-22 remain pending in this application. Claims 1-5 and 10-22 have been withdrawn from consideration as being directed to a non-elected invention.

Claims 6 and 9 have been amended to more particularly point out and distinctly claim what applicants regard as their invention. Specifically, each claim has been amended to point out that the vessel contains a freeze-dried composition in non-powder cake form. Support for this amendment can be found, for example, at page 22, lines 3-8, and page 52, lines 14-16, of the specification. Accordingly, no new matter has been introduced by these amendments.

### Specification

The new abstract was objected to because Applicants' submission allegedly does not indicate that the new abstract is a replacement paragraph or indicate the specific changes. On page 2 of the previous reply, Applicants provided a replacement Abstract indicating by underlining and strikethrough the changes made to the original Abstract. It would appear to Applicants that this amendment was in accordance with 37 C.F.R. § 1.121(b) and MPEP 714(II)(B). Applicants also provided a separate clean version of the Abstract which was unnecessary according to the stated MPEP section, but does not detract or render improper the appropriate amendment made to the Abstract. If this objection is continued, clarification of the requirement is requested.

### Objection:

Claim 6 has been objected to for repeating a phrase. This has been corrected by the present amendment.

Rejections: § 102

Claims 6-8 have been rejected under 35 U.S.C. § 102(a) or (e) as being anticipated by Yang (U.S. Patent No. 6,503,537), as evidenced by Ambrosio et al. (WO 94/14492). The Office argues that the non-powder form previously recited in these claims reads on the agglomerates or aggregates taught by Yang, which are not powders. According to the Office, the only structural limitation imparted by the product-by-process freeze-drying limitations is that the composition in the vessel is a solid composition, which is allegedly met by Yang's disclosure. The Office also concludes that Yang's composition must inherently exhibit the recited properties of disintegration index and becoming fine particles upon exposure to the recited air impact.

Claims 6-8 have been amended to more clearly point out that the freeze-dried composition in the vessel is in non-powder cake form that more clearly distinguishes the claimed invention over the teachings of Yang. The non-powder cake form of the freeze-dried composition of the present invention is different from the agglomerates of Yang at least because Yang requires agglomerates "formed in a highly repeatable, consistent manner with very little variation in terms of size, drug content and interparticle bond strength." (col. 6, lines 48-56). Any pieces of the freeze-dried cake that may be formed according to the present invention (see page 22, lines 2-15) would be random, irregular, and unnecessary to the present invention.

Unlike the present invention comprising a vessel housing a freeze-dried cake, Yang seeks a substantially uniform population of agglomerates that possesses a preselected amount of convertible amorphous content that can allow for the formation of generally crystalline agglomerates by exposing them to an appropriate stimuli (col. 4, lines 27-39). While Yang teaches (col. 8, lines 11-14) that the industry has long known

that an amorphous character may be imparted to certain unidentified materials by a variety of processes, Yang requires that at least part of these materials be converted to a crystalline form to produce agglomerates of relatively uniform size and size distribution (col. 7, lines 13-23).

Also contrary to the present invention, Yang further teaches that conversion of the agglomerates to a crystalline form is important because it provides a desirable balance in properties, allowing the agglomerates to be worked and manipulated without falling apart (col. 6, lines 48 to col. 7, line 23). As we understand the operation of the device described in Ambrosio et al. (see col. 15, lines 38-44 of Yang), the agglomerate particles break up as a result of physical impacts of the particles with walls and each other (see, e.g., page 40, line 22 to page 41, line 25 of Ambrosio et al.), not by an air impact. Accordingly, there is nothing in either one of the applied references that would suggest or provide any reason to believe that the agglomerates of Yang would satisfy the properties of the freeze-dried cake recited in these claims.

Finally, the Office has argued that the only structural limitation imparted by the product-by-process freeze-drying limitation is that the composition in the vessel is a solid composition. Applicants respectfully disagree because the process of freeze-drying results in a certain matrix of the composition containing ingredients in a non-dissolved form which is different than the population of agglomerates taught by Yang who emphasizes the importance of forming the agglomerates in a highly repeatable, consistent manner with very little variation in terms of size (see col. 6, lines 50-56). Nevertheless, applicants have amended claim 6 to more clearly point out that the freeze-dried composition in the vessel is in non-powder cake form, which clearly

distinguishes the claimed invention from the teachings of Yang. Accordingly, this rejection should be withdrawn.

Rejection: § 103

Claim 9 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang, as evidenced by Ambrosio et al., in view of Piper (U.S. Patent No. 5,533,502). In addition to the teachings relied on to reject claim 6, the Office relies on the teachings of Piper as showing some of the features of the claimed dry powder inhaler - e.g., conduits that communicate with the medicament container. However, Piper, like Yang, uses a medicament in particulate form where large particles are physically impinged on the walls of the inhalation device to be broken into smaller particles (col. 5, lines 44-46). For all the reasons discussed above in relation to claim 6, neither Yang, Ambrosio et al., nor Piper, alone or in combination, establish a prima facie case of obviousness of the subject matter of claim 9. Accordingly, this rejection should be withdrawn.

Double Patenting

Claims 6-9 are provisionally rejected on the ground of obviousness-type double patenting over claims 15-18 of copending Application 12/427,700. As the '700 Application has been abandoned, this rejection should be withdrawn as moot.

Prompt and favorable reconsideration of this application, and timely issuance of a notice of allowance are requested.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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